

REMARKS

Applicants acknowledge receipt of the Final Office Action dated February 24, 2004, in which the Examiner objected to certain of the previous amendments and rejected the claims 1-4, 6, 9-11, 13-16, 18-20, 22-25, 29, and 30-33 as anticipated by *Michelson* (U.S. Patent 6,537,320).

Applicants have amended the specification and claims to remove alleged new matter and has amended the claims to overcome the rejections over the art. For the reasons set out below, Applicants respectfully submit that the claims as amended are distinguishable over the art of record and therefore request that the rejections be withdrawn.

§ 112 Rejections

In the specification and claim 8, the term "the proteins described in U.S. Patent No. 5,290,763," that was added in the previous Response has been deleted.

Claims 34 and 36 have been canceled.

Applicants submit that these amendments cure the grounds for the § 112 rejections.

§ 102 Rejections

The Examiner has rejected claims 1-4, 6, 9-11, 13-14, 16, 18-20, 22-25, 29, and 30-33 as anticipated by *Michelson*.

Amended independent apparatus claims 1 and 11 and method claim 19 require a device that includes an "annulus-engaging" member, that seals the defect in the annulus upon insertion and prevents extrusions of the nucleus through the defect. *Michelson* not only fails to disclose, but instead teaches away from such a device. Applicant respectfully submits that these claims, as well as those depending therefrom, are patentable over *Michelson* as detailed below.

1. *Michelson does not teach engaging the annulus*

First, the sole means of engagement of the *Michelson* device with the spine of the patient is by means of the contact between its finned upper and lower surfaces and the adjacent vertebrae. The fins of *Michelson* gouge into the endplate of each vertebra and provide stability for the device once it is in place. (Col. 3, ll. 5-9, col. 3, ll. 55-60, col. 11, ll. 8-12). No contact with, much less a member to engage, the annulus is taught or suggested.

Indeed, Michelson teaches away from engaging the annulus. For example, Michelson teaches that disc material (i.e., including both the annulus and the nucleus pulposus) should be removed before his device is inserted. See, col. 5, ll. 51-57, "The method comprises the steps of: *removing at least a portion of the disc from between the adjacent vertebral bodies from vertebral endplate to adjacent vertebral endplate, and to a depth at least as great and preferably greater than the length of the implant, and to a width at least as great as the height of the implant as measured from fin tip to opposed fin tip where maximum for that implant.*" (emphasis added). With the disc material removed in this manner, there is not even a portion of the annulus that the Michelson device can engage.

2. *Michelson does not teach sealing a defect or preventing extrusion of the nucleus therethrough*

Rather than sealing an annular defect, as required in the present claims, Michelson teaches either de novo creation of a defect or expansion of an existing defect.

For example, Michelson specifically teaches that "The step of removing may include the step of exposing the endplates of the adjacent vertebral bodies by removing sufficient disc material including both annulus fibrosus and nucleus pulposus from between the adjacent vertebral bodies." Col. 18, ll. 63-67. Moreover, the above-noted absence of any annulus-engaging member prevents the device of Michelson from sealing the defect he teaches creating. Finally, Michelson teaches nothing about preventing extrusion of the nucleus through an annular defect. Instead, he teaches away therefrom by repeatedly emphasizing the replacement of damaged disc material with bone to fuse the adjacent vertebrae (i.e., thereby obviating the very structure and function of the nucleus).

Conclusion

For the reasons set out above, namely that

- *Michelson does not teach a device that engages the annulus;*
- *Michelson does not teach sealing an annular defect upon insertion of his spinal fusion implant; and*
- *Michelson does not teach preventing extrusion of the nucleus;*

Applicants respectfully submit that the claims as amended are allowable over the art of record. Applicants therefore request that the Examiner enter the amendments and reconsider and withdraw

the rejections. If the Examiner has any questions or comments, or otherwise feels it would be advantageous, she is encouraged to telephone the undersigned at (713) 238-8043.

Respectfully submitted,



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